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ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[EPA-HQ-OPP-2012-0903; FRL-9910-39]
Tricyclazole; Pesticide Tolerances
AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tricyclazole in or on imported rice. Dow AgroSciences, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0903, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You

must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0903, in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0903, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8114) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide tricyclazole, 5-methyl-1,2,4-triazolo[3.4-b] benzothiazole, including its metabolites and degradates, in or on rice at 3.0 parts per million (ppm). That document referenced a summary of the petition prepared by Dow AgroSciences, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Tricyclazole is a new active ingredient and is not currently registered or proposed for use in the United States. The only anticipated exposure to tricyclazole residues is from the dietary consumption of imported rice. Therefore, acute and chronic dietary assessments were conducted for tricyclazole residues of concern in food only.

Based upon review of the data supporting the petition, EPA has determined that the parent compound, tricyclazole, is suitable as a residue definition for purposes of both tolerance enforcement and risk assessment in rice. This determination is based on tricyclazole being the only major residue in rice grain and the observation that in samples from field trials with quantifiable levels of the alcohol metabolite, the metabolite is reduced to less than the level of detection upon husking. EPA has not revised the

tolerance proposed by Dow in the notice of filing. EPA has added the compliance statement which clarifies that only the parent compound is to be analyzed for enforcement purposes.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tricyclazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tricyclazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In oral rat and dog studies, decreased body weight was the primary effect observed in the database; in oral mouse studies, effects were mainly seen in the liver. In rats, decreased body weight was the only treatment related effect seen in adult animals in the subchronic and chronic studies, with body weight decreases occurring at a lower dose after chronic exposure. Decreased body weight was also seen in adult rats in developmental and reproduction studies. Other effects observed in rats included clinical signs (weakness, cold body, piloerection) in the developmental toxicity study at a dose similar to that in the subchronic study where decreased body weight was noted. Brain weight changes were also observed in rats in the chronic study; however, due to inconsistency in the data the effects were not considered treatment related. In dogs, decreased body weight was the only treatment related effect observed after chronic exposure. In mice, mortality was seen after 90 days, as well as hematological changes (increased WBC, decreased lymphocyte count, increased neutrophil) and liver effects (increased weights, enzymes, and histopathology). However, it is noteworthy to mention that the 90-day subchronic study was considered unacceptable due to numerous deficiencies. Increased mortality was not observed in other toxicity studies in mice. After 10 months, only liver effects (increased weights, microsomal activity, and histopathology) were observed in mice and no treatment related effects were observed

after 1 year. However, chronic exposure in mice (cancer mouse study), resulted in liver effects including, increased liver weights and liver histopathology (acidophilic degeneration and fatty change) at doses lower than those producing liver effects in the shorter term mouse studies.

Delayed ossification was observed in fetuses in the rabbit developmental study while decreased body weight was observed in fetuses in the rat developmental study. The effects were seen in the absence of maternal toxicity indicating quantitative susceptibility. In the rat reproduction study, offspring effects included pup death (post-natal day (PND 1-4)), decreases in pup body weight, and an increase in the number of small pups in the presence of less severe maternal toxicity (decreased body weight) indicating qualitative susceptibility. Although susceptibility was observed in the developmental/reproduction studies, the doses and endpoints selected for risk assessment are protective and the degree of concern for the susceptibility observed in the studies is low. The Agency has classified tricyclazole as "Not Likely to be Carcinogenic to Humans." There were no treatment-related increases in tumors observed in the submitted carcinogenicity studies in rats and/or mice.

Neurotoxicity (acute, subchronic, and developmental) and immunotoxicity studies are not available for tricyclazole. However, EPA, using a weight of the evidence (WOE) approach, concluded that these studies are not required. Dermal toxicity and dermal penetration studies are also not available for tricyclazole. However, these studies are not required to support import tolerances.

Specific information on the studies received and the nature of the adverse effects caused by tricyclazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* on pages 22-28, in the document titled, "Tricyclazole: Human Health Risk Assessment for the Establishment of Tolerances with No U.S. Registration for the New Fungicide in/on Imported Rice" in docket ID number EPA-HQ-OPP-2012-0903.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

Since the proposed uses of tricyclazole are all non-domestic, there is no potential for drinking water, occupational, and/or residential exposure, and the only anticipated exposure to tricyclazole is dietary exposure through consumption of imported rice. Therefore, endpoints and PODs were only selected for acute and chronic dietary risk assessment.

For acute dietary risk assessment (all populations including females 13-49), the no observed adverse effect level (NOAEL) of 7 milligrams/kilogram/day (mg/kg/day) was selected from a reproduction study in rats. An increased incidence of pup death was seen at the lowest observed adverse effect level (LOAEL) of 26.7 mg/kg/day. Decreased pup weight and small pups were also observed at the LOAEL but were not considered to be single dose effects.

For chronic dietary exposure, a NOAEL of 6.67 mg/kg/day was selected from a cancer study in mice based on liver effects observed at the LOAEL of 21.8 mg/kg/day. For acute and chronic dietary risk assessments, a 100X uncertainty factor was applied (interspecies factor of 10X and intraspecies factor of 10X).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to tricyclazole, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from tricyclazole in food as follows:

i. *Acute and chronic exposure*. Acute and chronic dietary (food only) exposure assessments were conducted with the Dietary Exposure Evaluation Model (DEEM-

FCID), Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). Conservative acute and chronic exposure analyses were performed for the general U.S. population and population subgroups. Recommended tolerance-level residues were used to estimate dietary exposure. The analyses assumed 100% of imported rice is treated.

ii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that tricyclazole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iii. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for tricyclazole. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found tricyclazole to share a common mechanism of toxicity with any other substances, and tricyclazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tricyclazole does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicological database is complete with regard to pre-and postnatal toxicity. Although there was evidence of quantitative susceptibility in developmental rat and rabbit toxicity studies and qualitative susceptibility in the reproduction study, the degree of concern for the effects observed in the studies is low. There are clear NOAELs/LOAELs for the fetal/pup effects seen and the effects in the developmental and reproduction studies were observed at levels significantly higher than the current PODs selected for risk assessment. Therefore, the acute and chronic dietary risk assessments are protective of potential fetal/offspring effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for tricyclazole is complete with regard to pre- and postnatal toxicity.

ii. The endpoints and doses selected for risk assessment are protective of the increased qualitative susceptibility observed in the reproduction study in rats and the increased quantitative susceptibility seen in the developmental rat and rabbit studies; therefore the degree of concern for the susceptibility is low.

iii. The endpoints and doses selected for risk assessment are also protective of the observed clinical signs in the database and neurotoxicity studies (acute, subchronic, and developmental) are not required; an immunotoxicity study is also not required.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. These assessments will not underestimate the exposure and risks posed by tricyclazole.

IV. Other Considerations

A. Analytical Enforcement Methodology

Three methods have undergone successful independent laboratory validation for use as enforcement analytical methods. The first method is suitable for the analysis of both parent tricyclazole and the alcohol metabolite. It involves acid hydrolysis, extraction of residues into dichloromethane, clean-up by strong cation exchange (SCX) solid-phase extraction, silylation of the alcohol metabolite, and analysis by gas

chromatography/mass spectrometry (GC/MS). The validated limit of quantitation (LOQ) is 0.02 ppm for rice grain, polished rice, and rice husks, and 0.05 ppm for rice forage, straw, and processed byproducts. The remaining two methods are multi-residue methods (DFG S19 and modified QuEChERS). DFG S19 uses acetone extraction, clean-up by partitioning and gel-permeation chromatography (GPC), and analysis by GC-MS. The validated LOQ is 0.02 ppm (parent only). The modified QuEChERS method uses acetonitrile/water extraction, clean-up by solid-phase partitioning, and analysis by liquid chromatography/mass spectrometry (LC-MS/MS). The validated LOQ is 0.01 ppm each for the parent compound and the alcohol metabolite.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA

explain the reasons for departing from the Codex level. The Codex has not established a MRL for tricyclazole in rice.

C. Revisions to Petitioned-for Tolerances

EPA has not revised the tolerance levels, added or deleted tolerances, or otherwise modified the petition as proposed in the notice of filing. However, EPA has added the compliance statement which clarifies that the parent compound, tricyclazole, it so be measured for enforcement purposes.

V. Conclusion

Therefore, a tolerance is established for residues of tricyclazole, 5-methyl-1,2,4-triazolo[3,4-b] benzothiazole, including its metabolites and degradates, in or on rice, grain at 3.0 ppm. Compliance with the tolerance is to be determined by measuring only tricyclazole.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction

Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 29, 2014.

Jack Housenger,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.678 is added to subpart C to read as follows:

§ 180.678 Tricyclazole; tolerances for residues.

(a) *General*. (1) Tolerances are established for residues of the fungicide tricyclazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only tricyclazole (5-methyl-1,2,4-triazolo[3,4-b]benzothiazole).

Commodity	Parts per million
Rice, grain[1]	3.0

[1]There are no U.S. Registrations on Rice as of [*insert date of Publication in* **Federal Register**].

(b) *Section 18 emergency exemptions*. [Reserved]

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

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